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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/206,249	12/07/1998	MIRI SEIBERG	JBP438	5255

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/206,249

Applicant(s)

SEIBERG ET AL.

Examiner

Michael V. Meller

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,28-36,38,40,44-47 and 58 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,28-36,38,44-47 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 40, 44-47, 58 (the parts of 44-47 and 58 that have to do with prevention).

DETAILED ACTION

Election/Restrictions

The election of species of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 24, 28-36, 38, 44-47, 58 drawn to a method of treating a mammal, classified in class 424, subclass various.
- II. Claims 40, 44-47, 58 drawn to a method of preventing a mammal from a disease, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

The inventions are restrictable from one another since a method of treatment requires that the condition already exist whereas the method of preventing does not require the condition to already exist on the patient in need thereof.

Art Unit: 1655

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Andrea Colby on 9/12/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 24, 28-36, 38, 44-47, and 58. Affirmation of this election must be made by applicant in replying to this Office action. Claims 40 and the parts of claims 44-47, and 58 having to do with prevention are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

Claims 24, 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. (abstract, table 1, page 7, example 3) or Ikeda et al. (abstract, table 1, results section, page 87).

Applicant argues that Limtrakul does not apply the same composition as applicants because applicant argues that the soybean milk of Limtrakul must have had

Art Unit: 1655

the STI inactivated because otherwise it would not have been suitable for the mouse to ingest.

Nowhere in Limtrakul do they say that the STI in the soybean milk was inactivated. Thus, the same composition as applicants was given to the mice in Limtrakul.

Further, it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk.

Thus, the reference clearly teaches administration of the composition to a mammalian cell.

Applicant argues that soy products containing soy trypsin inhibitor activity were well known to be dangerous for human ingestion. While this is noted, as noted above nowhere in Limtrakul do they ever say that the STI in the soybean milk was inactivated. The declaration by Katherine Martin may say that the raw soybeans causes gastric distress but this in and of itself does not mean that the soybeans are inedible. Further as stated before tofu is soybeans which are routinely consumed by people and does not cause gastric distress. Applicant argues that the tofu is cooked but there is no evidence of this on the record.

Applicant argues again that the Martin declaration filed 3/18/2002 establishes that soybeans must be heated to be consumed but the soybean milk is applied topically not orally. There is no need to ingest the soybean milk only apply it topically.

Art Unit: 1655

Ikeda teaches administering soybean milk to psoriatic skin (which contains cells). Psoriasis is a skin condition which would require the claimed method. Thus, the claims read on treating psoriasis.

Claims 24, 28-36, 38, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62036304 (applicant notes this reference as Katsumi).

JP teaches a composition containing soybean milk which is applied to the skin. The translation of JP makes it clear that water can be added to the soybean milk and applied to the forehead, arms or hands.

All the claims require is that the soybean milk is administered to the cells which the reference does indeed teach.

Applicant argues again that the Martin declaration filed 3/18/2002 establishes that soybeans must be heated to be consumed but the soybean milk is applied topically not orally. There is no need to ingest the soybean milk only apply it topically.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

Art Unit: 1655

being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 28-36, 38, 44-47 and 58 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/110,409 which has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

Applicant's comments concerning this rejection are not well taken. Applicant even admits that the inventive entities are one and the same as the instant application and that of 09/110,409. Thus, it is not understood what applicant is arguing.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

Claims 24, 28-36, 38, 44-47, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with JP 62036304.

This rejection is of record and has been argued already on the record. Limtrakul does not teach administering to a human the soybean milk. JP makes it clear that soybean can administered to a human, see JP, page 7, example 3.

Claims 24, 28-36, 38, 44-47, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. taken with JP 62036304.

Ikeda does not teach administering to a human the soybean milk. Ikeda teaches administering soybean milk to psoriatic skin. JP makes it clear that soybean can administered to a human, see JP, page 7, example 3.

Double Patenting

Claims 24, 28-36, 38, 44-47 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 09/110,409. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims have not in fact been patented.

Without the terminal disclaimer, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1655

MVM